JUL 14 2003 K031181

510(k) Summary of Safety and Effectiveness
External Fixation Systems

Submitted by:	Smith & Nephew, Inc. Orthopaedic Division 1450 Brooks Road Memphis, TN 38116
Date:	April 14, 2003
Contact Person:	David Henley Senior Clinical / Regulatory Affairs Specialist
Proprietary Name:	External Fixation Systems
Common Name:	External Fixation Accessories
Classification Name and Reference:	Smooth or threaded metallic bone fixation fastener, 21 CFR 888.3040, Class II
Device Product Code and Panel Code:	KTT / Orthopedics / 87

Device Description:
External fixation devices, such as the external fixation bar clamps and pin clamps described herein, are specially designed components used in the management of bone fractures and reconstructive, as well as corrective, orthopedic surgery. The metal alloys used in their manufacture are chosen to address a wide range of applications. These devices have been designed to allow for the appropriate amount of rigidity and stability.

Intended Use:
External Fixation System components are intended to be used on adults or pediatric patients as required and are intended to be used for fracture fixation (open and closed); post-traumatic joint contracture which has resulted in loss of range of motion; fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction; pseudoarthrosis or non-union of long bones; limb lengthening by epiphyseal or metaphyseal distraction; correction of bony or soft tissue deformity; correction of segmental bony or soft tissue defects; joint arthrodesis; and management of comminuted intra-articular fractures of the distal radius.

Technological Characteristics:
The principle of operation of these reprocessed devices is very similar to that of the predicates. There are no changes in intended use, performance specifications or method of operation. The reprocessed devices utilize similar designs, the same materials and technological characteristics when compared to the predicate devices.

Substantial Equivalence Information:
The intended use of the reprocessed external fixation bar clamps and pin clamps is identical to that of the Smith & Nephew Unilateral Fixator (K994143) and the Smith & Nephew Unilateral Wrist Fixator for Distal Radius Fractures (K994143). The design and the function of the subject devices are very similar to the predicate devices and they are manufactured from the same materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 14 2003

Mr. David Henley
Senior Clinical and Regulatory Affairs Specialist
Smith & Nephew, Inc.
1450 Brooks Road
Memphis, Tennessee 38116

Re: K031181
Trade/Device Name: External Fixation Systems
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: KTT
Dated: April 14, 2003
Received: April 15, 2003

Dear Mr. Henley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D. for
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) number (if known): K031181

Device Name: External Fixation Systems

Indications for Use:

External Fixation System components are intended to be used on adults or pediatric patients as required and are intended to be used for fracture fixation (open and closed); post-traumatic joint contracture which has resulted in loss of range of motion; fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction; pseudoarthrosis or non-union of long bones; limb lengthening by epiphyseal or metaphyseal distraction; correction of bony or soft tissue deformity; correction of segmental bony or soft tissue defects; joint arthrodesis; and management of comminuted intra-articular fractures of the distal radius.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

MRO for CMW

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031181

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-the-Counter Use _____
(Optional Format 1-2-96)